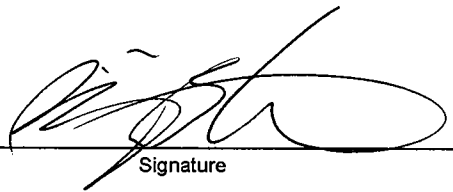


Doc Code: AP.PRE.REQ

PTO/SB/33 (07-05)

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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) 112713-457	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on _____ Signature _____ Typed or printed name _____		Application Number 10/738,446	Filed December 16, 2003
		First Named Inventor Kelly et al.	
		Art Unit 3761	Examiner Leslie R. Deak
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <div style="display: flex; justify-content: space-between; align-items: flex-start; margin-top: 20px;"><div style="width: 45%;"><p>I am the</p><p><input type="checkbox"/> applicant/inventor.</p><p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p><p><input type="checkbox"/> attorney or agent of record. Registration number _____</p><p><input checked="" type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 <u>54,050</u></p></div><div style="width: 50%; text-align: center;"> _____ Signature Benjamin B. Cotton _____ Typed or printed name 312-781-6020 _____ Telephone number December 28, 2006 _____ Date</div></div> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>			
<p><input type="checkbox"/> *Total of _____ forms are submitted.</p>			

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: THOMAS D. KELLY, ET AL.
Appl. No.: 10/738,446
Filed: DECEMBER 16, 2003
Title: MEDICAL FLUID THERAPY FLOW CONTROL SYSTEMS AND METHODS
Art Unit: 3761
Conf. No.: 8102
Examiner: DEAK, LESLIE R.
Docket No.: DI-5928 (112713-457)

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Dear Sir/Madam:

This request is submitted in response to the Advisory Action dated **December 20, 2006**. This request is filed contemporaneously with a form PTO/SB/33, "Pre-Appeal Brief Request for Review" and a form PTO/SB/31, "Notice of Appeal."

Remarks begin on page 2 of this paper.

REMARKS

This request and remarks are submitted in response to the interpretation of the prior art maintained in the final Office Action dated August 28, 2006 and the Advisory Action dated December 20, 2006, which Applicants respectfully believe rises to the level of clear error, making the case proper for pre-appeal review. Because this Response is submitted with a Petition for a one (1) month Extension of Time ("EOT") and corresponding fees on or before the period for reply set to expire on **December 28, 2006**, this Response is timely filed.

A check in the amount of \$500.00 is submitted herewith to cover the fee for the Notice of Appeal set forth under 37 C.F.R. §41.20(b)(1). The total fees believed due in connection with this Response and the Notice of Appeal are \$620.00, however, please charge **Deposit Account No. 02-1818** for any additional fees deemed owed.

Claims 1 to 107 are pending in this application, with claims 1 to 13 and 39 to 107 having been withdrawn from consideration. Thus, Claims 14 to 38 are pending and at issue in this application.

In the Office Action, Claims 14 to 20 and 33 to 37 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,470,483 to Bene et al. ("*Bene*"). In the "Response to Arguments" section of the Office Action dated August 28, 2006, the Examiner states that "[p]ump 11 is 'operable to,' that is capable of halting pump operation, thereby isolating the filter 4 from the medical fluid supply 10."

In the Response to Final, Applicants point out that:

Claim 14 calls for an apparatus operable to isolate the blood filtering device from the rest of the medical fluid flow path. It does not require the apparatus to isolate the supply from the extracorporeal circuit. Pump 11 does just that, and by doing so it precludes the delivery of fluid from supply 10 to the extracorporeal circuit.

Applicants have responded to Examiner's assertion that pump 11 of *Bene* satisfies the limitation relating to isolating the filter from the rest of the medical fluid flow path.

In the Advisory Action, the Examiner has now indicated that pump 11 was not named as the isolating device but that clamps 17, 18 of *Bene* satisfy the isolating device. Applicants maintain that *Bene* fails to teach each of the limitations of independent Claim 14 and Claims 15 to 38 which depend therefrom, and the

Examiner's assertion that either pump 11 or clamps 17, 18 act to isolate the blood filtering device from the rest of the medical fluid flow path amounts to clear error.

In particular, as previously explained, pump 11 of *Bene* does not operate to isolate the blood filtering device from the rest of the medical fluid flow path. Instead, pump 11 selectively isolates the supply of medical fluid from the extracorporeal circuit. However, Claim 14 of the present application requires an apparatus operable to isolate the blood filtering device from the rest of the medical fluid flow path. Pump 11 does not isolate the blood filtering device from the medical fluid flow path. The Examiner asserts in the final Office Action that pump 11 of *Bene* isolates the filter from the medical fluid supply, but Claim 14 does not require the blood filter to be isolated from the medical fluid supply.

Additionally, clamps 17, 18 of *Bene* also fail to satisfy an apparatus operable to isolate the blood filtering device from the rest of the medical fluid flow path. Clamps 17, 18 isolate the entire medical fluid flow path from the patient, which the Examiner explained in the Advisory Action. If the clamps 17, 18 were activated, there would be no medical fluid flow path from which the filter is being isolated. Instead, the medical fluid flow path is isolated from the patient. However, Claim 14 includes an apparatus for isolating the blood filtering device from the rest of the medical fluid flow path and not an apparatus for isolating the medical fluid flow path from the patient. Accordingly, Applicants assert that the Examiner has failed to provide a *prima facie* showing that *Bene* teaches an apparatus that isolates the blood filtering device from the rest of the medical fluid flow path. The Examiner has now provided two separate devices in *Bene* as teaching an isolating device, but neither satisfies the limitation of Claim 14.

Furthermore, the Examiner has reiterated that the "Bene device is capable of isolating filter device 4 from the patient, not the medical device supply [sic] 10. The Nonfinal Rejection pointed out that the Bene device is capable of isolating the circulating blood from the patient, while the Final Rejection points out that the Bene device is capable of isolating the filter from the patient." The Examiner continues to point out isolation of the blood filter from the patient. However, Claim 14 does not require the isolation of the filter from the patient. Instead, Claim 14 includes "an apparatus operable to isolate the blood filtering device from the rest of the medical fluid flow path" (emphasis added). Without providing a device in *Bene* that isolates

the blood filtering device from the rest of the medical fluid flow path, the Examiner has failed to provide a *prima facie* showing to support a rejection under 35 U.S.C. § 102(b) over *Bene*.

For the foregoing reasons, Applicants assert that the pending claims are in condition for allowance, and request issuance of a Notice of Allowance of claims 14 to 38.

Respectfully submitted,

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Date: **December 28, 2006**